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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/838,382	**Applicant(s)** DANFORTH ET AL.	
	Examiner Ja-Na Hines	**Art Unit** 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 February 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *24 February 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *14 and 15*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *16*.
   Claim(s) withdrawn from consideration: *1-13*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

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The written description rejection of claim 16 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record. The rejection was on the grounds that the written description in this case fails to set forth a variant strain of Eimeria maxima wherein said variant corresponds in characteristics to the strain E. maxima-I (ATCC number PTA-4959) as set forth in claim 15.

Applicants assert that variant strains of parasites cannot be described by nucleic aicd structure, rather they are described by their existence and by their identifying characteristics. However it is unclear where such standards are stated with respect to overcoming the written description rejection or receiving a patent. Thus, it is suggested that the instantly claimed variant strain be deposited to overcome the rejection.

Applicants assert that examples 3-6 teach other strains dervied according to the immunological selection methods. However, the issue is not about whether one skilled in the art would know how to dervie other strains, or analyze the claimed characteristics of a variant strain of E. maxima to determine its correspondence to E. maxima-I. The issue is that the specification and the claims fail to teach the identity of a variant strain that is not ATCC-PTA 4959 yet corresponds in characteristics to the strain E. maxima-I (ATCC number PTA-4959). Thus, applicants statements are not persaussive when the statements merely suggest that other strains exist, yet applicant failed to isolate these strains, characterize these strains or deposit these strains.Therefore, applicant has still not shown possession of these immunovariant strains.

Applicants' assert that given the guidance of the specification and claims, one of skill in the art would know whether these characteristics correspond to E. maxima-I. The function of the description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied on, the specific subject matter later claimed by him or her; how the specification accomplishes this is not material. Applicants have failed to show that they were in possession of the variant strain claimed in claim 16.

Applicants assert that variant strains exist. However, example 6 of the instant specification only teaches that strain ATCC PTA-4959 has the characteristic that upon immunization with E.maxima –I (ATCCC number PTA-4959) the strain protects against challenge with E. maxima-I (ATCC number PTA-4959), but does not protect against challenge with E. maxima-GLP, as an indication that said variant strain has no detectable immunological cross reactivity with E.maxima-GLP. The example and specification state that the other strains tested by applicants' such as the MSS strain failed to have the required characteristics. Moreover, applicants' state that other strains known in the art such the strains disclosed by Martin et al., and Barta et al., fail to have the requisite corresponding characteristics. Moreover, pages 8, 14-16 and 18 of the instant specification fail to disclose a variant strain that corresponds in characteristics to the strain E. maxima-I (ATCC number PTA-4959) wherein immunization with said variant strain or E.maxima –I (ATCCC number PTA-4959) protects against challenge with said variant strain or E. maxima-I (ATCC number PTA-4959), but does not protect against challenge with E. máxima-GLP, an indication that said variant strain has no detectable immunological cross reactivity with E.maxima-GLP. Thus, there is evidence that other variant strains known in the art do not have the required characteristics. oreover, the examiner has mmet the burden of showing by a ponderance of evidence that a person skilled in the art would not recognize in applicants' disclosure a descripiton of the invention defined by claim 16. The burden is met because applicants' themselves disclose several strains derived by the selection process which failed to produce qualifying strains. Thus, one skilled in the art could not recognize the instantly claimed invention.

Applicants' have failed to disclose support for the variant strain of claim 16; rather applicants' have disclosed some characteristics of the unidentified strain. The instant specification and claims describe a variant strain of Eimeria maxima wherein said variant corresponds in characteristics to the strain E. maxima-I (ATCC number PTA-4959) by its function i.e., immunization and cross-reactivity abilities, however this description does not describe the claimed variant strain itself, nor does it provide the identity of the strain.
There is evidence that other variant strains known in the art do not have the required characteristics. There is no teaching in the specification that discloses the identity of a variant strain that has the claimed characteristics to thereby indicate that said variant strain has no detectable immunological cross reactivity with E.maxima-GLP
A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process as is the case here. Applicants' specification continuously point out strains that do not meet the claimed limitations, with the exception of the deposited strain. Thus one of skill in the art could not immediately envision the claimed variant strain. Similarly, it appears that the instant case sets forth an undisclosed variant strain and asserts that this undisclosed strain has some functional limitations. However, there is no actual disclosure of the claimed variant strain. Moreover, the functional limitations do not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species.
Therefore the rejection is maintained because applicants' arguments are not persuasive and because applicants' have failed to provide support that they were in possession of this variant strain as claimed.

The new matter rejection of claim 16 under 35 U.S.C. 112, first paragraph, is maintained for reasons already of record.
Applicants' statements are not persuassive, since applicants response fails to disclose page and line number support, in response to the new matter rejection. Moreover, neither the specification nor originally presented claims provide support for a variant strain of Eimeria maxima wherein said variant corresponds in characteristics to the strain E. maxima-I (ATCC number PTA-4959) as set forth in claim 15 wherein: immunization with said variant strain or E.maxima –I (ATCCC number PTA-4959) protects against challenge with said variant strain or E. maxima-I (ATCC number PTA-4959), but does not protect against challenge with E. maxima-GLP, an indication that said variant strain has no detectable immunological cross reactivity with E.maxima-GLP. It is noted that the examples and original claims fail to disclose the identity of a variant strain that is not the deposited strain ATCC PTA-4959 having the claimed characteristics. Thus, there appears to be no teaching of a variant strain of Eimeria maxima wherein said variant corresponds in characteristics to the strain E. maxima-I (ATCC number PTA-4959) as set forth in claim 15. Therefore, it appears that there is no support in the specification or original claims. Therefore, claim 16 incorporates new matter and the rejection is maintained.

REMARKS/ARGUMENTS

1. Claims 3-16 were previously pending. Claims 3-13 were withdrawn from consideration by the Examiner, as being drawn to a non-elected invention. Claims 14 and 15 have been allowed. Claim 16 has been rejected.

Applicants hereby request further examination and reconsideration of the application, in view of the remarks.

2. • Claims 16 has been rejected under 35 U.S.C. 112, first paragraph.

Rejections of Claim 16 under 35 U.S.C. 112, first paragraph

3. The Examiner has rejected Claim 16 under 35 U.S.C. 112, first paragraph, "as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."

The Examiner states that the written description rejection of Claim 16 "was on the grounds that the written description in this case fails to set forth a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima-I* (ATCC number PTA-4959) as set forth in claim 15" (Page 2; Section 4, Paragraph 1) and that the "function of the description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied on, the specific

subject matter later claimed by him or her; **how the specification accomplishes this not material"** (Page 3, Lines 8-11).

The Examiner further asserts, "Applicants' have not shown that they were in possession of a variant strain of *Elmeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959)" (Page 3, Lines 17-20); "an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of the invention" (Page 4, Lines 3-5); "Applicants' have not even pointed to support for the variant strain of claim 16" (Page 4, Lines 19-20); "Possession may be shown in a variety of ways including description of an actual reduction to practice, ... or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (Page 5, Lines 3-7); "functional limitations alone are not sufficient to satisfy the written description requirement" (Page 5, Lines 10-12); and "A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process as is the case here... one of skill in the art could not immediately envision the claimed variant strain" (Page 5, Lines 13-15).

The Examiner concludes, "it appears that the instant case sets forth an undisclosed variant strain and asserts that this undisclosed strain has some functional limitations. However, there is no actual disclosure of the claimed variant strain. Moreover, the functional limitations do not constitute a written description of every species in a genus because it would not 'reasonably lead' those skilled in the art to any particular species" (Page 6, Lines 12-17).

Applicant respectfully traverses the rejection. A variant strain of parasite cannot be described by nucleic acid structure. Cell lines, and here a parasitic strain, are described

by their existence and by their identifying characteristics and not by their DNA sequence.

The instant specification discloses that "[T]he invention includes the immunovariant strain *E. maxima*-I, exemplified in Examples 3-6, individually and its use in vaccinating chickens against a coccidial infection. In a preferred embodiment, the present invention encompasses any strains that correspond in characteristics to the line *E. maxima*-I and other strains derived according to the immunological selection method of the invention. The invention includes such sub-lines of the above strain (having been derived from the same parent) or descendants therefrom (having been derived from the deposited lines by further passaging). The immunovariant strain of the invention can be used individually or in any combination of the strain of the invention with one or more other live or attenuated *Eimeria* organisms, in any proportions. The invention further includes feed or drink, including water, containing parasites of the line" (Page 9, Lines 7-17). The instant specification further discloses other immunovariants having the same characteristics as strain *E. maxima* -I, *e.g.*, in Example 3, *In vivo* Selection of the Immunovariant Strain *E. maxima* -I): "[B]irds immunized by oral infection with the Guelph strain of *E. maxima* (*E. maxima*-GLP) were challenged with the Florida strain. The resulting oocysts were sporulated and then passaged through additional birds immunized against the Guelph strain. Four such passage collections, **using oocysts collected from each preceding passage, were used to challenge the next group of immunized birds and selected for a strain of *E. maxima*, designated *E. maxima* -I, that was totally immunovariant from the *E. maxima*-GPL.** Birds immunized against the Guelph strain no longer recognized the resulting immunovariant *E. maxima* strain, *E. maxima* -I" (Page 14, Lines 15-22). Oocysts having the same identifying characteristics as strain *E. maxima* -I are present in the passage collections disclosed in

Example 3. As can be seen from the numbers of oocysts disclosed in Table 1, the procedure will generate immunovariant strains having the same identifying characteristics as strain *E. maxima* -I. The instant specification discloses that immunovariant strains exist and that the selection process will yield immunovariant strains as shown in Example 3, Table 1, and the disclosure, "Table 1 shows that *E. maxima* -GPL-immunized birds shed as many oocysts after challenge with the *E. maxima* -I strain as did the non-immunized birds challenged with *E. maxima* -I, indicating no cross-protection. In contrast, the *E. maxima*- GPL- and *E. maxima* -I - immunized birds shed zero or very few oocysts after homologous challenge" (Page 16, Lines 1-5).

Claim 15 recites the distinguishing characteristics by which the variants are distinctly recognizable or known, *i.e.*, those characteristics which are commonly shared by *E. maxima*-I and the variant. Claim 15 recites, "[T]he variant strain *E. maxima*-I (ATCC number PTA-4959) of Claim 14 which is further identified by the characteristic wherein: immunization with *E. maxima*-I (ATCC number PTA-4959) protects against challenge with *E. maxima*-I (ATCC number PTA-4959) but does not protect against challenge with the Guelph strain of *E. maxima*, designated *E. maxima*-GLP, an indication that *E. maxima*-I (ATCC number PTA-4959) has no detectable immunological cross reactivity with *E. maxima*-GLP. Claim 16 recites, "A variant strain of *Eimeria maxima* wherein said variant strain corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in Claim 15 wherein: immunization with said variant strain or *E. maxima*-I (ATCC number PTA-4959) protects against challenge with said variant strain or *E. maxima*-I (ATCC number PTA-4959), but does not protect against challenge with *E. maxima*-GLP, an indication that said variant strain has no detectable

Immunological cross reactivity with *E. maxima*-GLP.

Thus, the specification teaches that variant strains of *Eimeria maxima* wherein said variant strain corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) exist, Claim 15 recites the distinguishing characteristics by which the variants are distinctly recognizable or known, *i.e.*, those characteristics which are commonly shared by *E. maxima*-I and the variant, and Claim 16 recites said variants, the variant strains of *Eimeria maxima* wherein said variant strain corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959).

According to the MPEP (2163.04), a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. The inquiry into whether the description requirement is met must be determined on a case-by-case basis. The Examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.

Applicant contends, as discussed *supra*, that there is support for the claimed invention in the specification and that, therefore, a person skilled in the art would recognize a description of the invention as defined by Claim 16. Applicant respectfully submits that the Examiner has not met the burden.

In view of the above remarks, it is respectfully requested that the rejection under 35 U.S.C. paragraph 112, first paragraph, written description, be withdrawn.

4. The Examiner has rejected Claim 16 under 35 U.S.C. 112, first paragraph, "as falling to comply with the written description requirement. This is a new matter rejection." The Examiner asserts that the "issue of a lack of adequate written description and new matter may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention" (Page 7, Lines 8-11). The Examiner states that "it is noted that the examples and original claims fail to disclose the identity of a variant strain that is not the deposited strain ATCC PTA-4959 having the claimed characteristics. Therefore, it appears that there is no support in the specification or original claims" (Paragraph bridging Pages 8 and 9).

Applicant respectfully traverses the rejection. No new matter has been introduced by Claim 16. Applicant contends that claimed invention has been described with sufficient particularity such that one skilled in the art would recognize that the Applicant had possession of the claimed invention and has particularly pointed, *supra*, to support in the specification for the claimed invention. As stated above, according to the MPEP (2163.04), a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. The Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Applicant respectfully submits that the Examiner has not met the burden.

In view of the above remarks, it is respectfully requested that the rejection under 35 U.S.C. paragraph 112, first paragraph, written description, new matter, be withdrawn.

CONCLUSION

The office action was mailed on November 24, 2004, and this response is submitted within the three month period for reply, therefore no extension of time is required and no fee is due. Please charge any additional fees which may be required at any time during prosecution of the instant application to deposit account 50-2134.

Applicants appreciate the Examiner's allowance of Claims 14 and 15. It is believed that all of the claims and the specification are in condition for allowance. Accordingly, it is respectfully requested that the rejections be withdrawn and that the instant application be allowed to issue. If any issues remain to be resolved, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

February 24, 2005 Evelyn M. Rabin
Date

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d. challenging *E. maxima*-GLP-immunized birds with said recovered oocysts;

e. recovering oocysts;

f. repeating steps d and e at least one time; and

g. obtaining an immunovariant strain of *E. maxima*.

Claim 13 (withdrawn): An immunovariant strain of *Eimeria maxima* isolated by the method of Claim 10.

Claim 14 (previously presented): A variant strain of *Eimeria maxima*, said variant strain is designated *E. maxima*-I and is deposited under the ATCC accession number PTA-4959.

Claim 15 (previously presented): The variant strain *E. maxima*-I (ATCC number PTA-4959) of Claim 14 which is further identified by the characteristic wherein:

immunization with *E. maxima*-I (ATCC number PTA-4959) protects against challenge with *E. maxima*-I (ATCC number PTA-4959) but does not protect against challenge with the Guelph strain of *E. maxima*, designated *E. maxima*-GLP, an indication that *E. maxima*-I (ATCC number PTA-4959) has no detectable immunological cross reactivity with *E. maxima*-GLP.

Claim 16 (previously presented): A variant strain of *Eimeria maxima* wherein said

variant strain corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in Claim 15 wherein:

> immunization with said variant strain or *E. maxima*-I (ATCC number PTA-4959) protects against challenge with said variant strain or *E. maxima*-I (ATCC number PTA-4959), but does not protect against challenge with *E. maxima*-GLP, an indication that said variant strain has no detectable immunological cross reactivity with *E. maxima*-GLP.